REMARKS

1. Amendments to the Specification

The Specification is herein amended to remove plain typographical errors. No new matter has been added.

2. Amendments to the Claims

Claims 1, 4, 6-11 and 13-27 are pending. Claims 1, 10, 18, 19, 20, 22, and 23 are herein amended. Claims 24-27 have been added.

The amendment to claims 1, 10, 19, and 20 is supported by the Specification at pages 2, lines 1-24. Further support for this limitation is discussed below.

The amendment to claim 18 is supported by the Specification at page 2, line 19 - medicaments "induce an unpleasant taste".

The amendment to claims 22 and 23 is supported by the Specification at page 19, lines 18-23.

New claims 24-27 are similar to the independent claims of record, but more specifically recite the ingredients including binders, fluidization agents, a corrigant, and a disintegrant. Support for these additions is found in the Specification at page 19, lines 18-23 and page 21, lines 12-17.

No new matter has been added.

3. Interview Summary

Applicants sincerely thank the Examiner for granting their representatives the courtesy of an Interview. Applicants' Representative spoke with Examiner Huang on December 15, 2009 and discussed the prior art of record. Though no agreement was reached, Applicants again thank the Examiner for her time and consideration.

4. **Claim Rejections**

a. Written Description

The Examiner rejects claims 1, 4, 6-11, and 13-23 under 35 U.S.C. § 112, first paragraph, as not being supported by adequate written description, such that the amendments constitute new matter. The Examiner states that "the claims recite an intended use comparison in regards to techniques such as coating and microcapsulation". The Examiner states that the disclosure does not address the negative comparative for coating or microcapsulation techniques and also does not describe what microcapsulation forms are encompassed." (Office Action, pages 2-3). Applicants submit that the negative limitation has been removed from the claims. Thus, the rejection has been obviated. Applicants request that the rejection be withdrawn.

b. **Obviousness**

Siebert

The Examiner rejects claims 1, 4, 6-7, 11, 13-20, and 22-23 under 35 U.S.C. § 103 as unpatentable over Siebert et al. Applicants respectfully traverse.

The Examiner first indicates that since the "particles" in the specification, at page 21, can contain additional excipients and is a solid form, it is viewed as the same as a granule or powder with the same components which are taught by Siebert. (Office Action, page 5). Applicants respectfully disagree.

i. The basic and novel characteristics of the invention are a lack of an unpleasant taste.

Claims 1, 10, 19, and 20 recite "consisting essentially of". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz,*

537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). (See MPEP 2111.03). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Applicants submit that the Specification defines the basic and novel characteristics of the claimed invention. Specifically, the Specification indicates that the invention is related to "a medicament-particle wherein the unpleasant taste of the medicament having the unpleasant taste is alleviated" and a solid preparation containing the particle which "has a good dissolvability in the gastrointestinal tract." (Page 1, lines 9-15). The Specification describes how others have attempted to solve these problems by adding sweeteners or a flavor (page 2, line 4), or by coating the medicament or medicament-containing granule (page 2, lines 6-9). However, the Specification describes that sometimes it is necessary to add a large amount of sweetener to mask the taste, or provide multiple coatings. With the coatings, the Specification indicates that "the coating may affect a releasing amount of the medicament transferred into the gastrointestinal tract and the desired release of the medicament can not be obtained." (Specification, page 2, lines 12-15). The Specification reiterates that "it is difficult to simultaneously satisfy above the two conditions of rapid disintegrability in buccal cavity and alleviation of an unpleasant taste in buccal cavity . . . and it is furthermore difficult to simultaneously satisfy the condition of alleviating an unpleasant taste in bucall cavity and the condition of good dissolubility in gastrointestinal tract." (page 2, line 21 to page 3, line 4).

Accordingly, the term "consisting essentially of" in the claims excludes unnamed materials from the claims that mask the unpleasant taste of the medicament.

ii. The claims are different from Siebert in the point of masking taste.

Applicants submit that Siebert includes ingredients which mask the unpleasant taste of the medicament. In particular, Applicants point to Siebert col. 3, lines 50-55, which indicates that a coating on the powders is intended to "assist in providing effective taste masking". While Siebert indicates that powders need not be coated, in practice Siebert suggests that if taste masking was intended, the powder should be coated. (Siebert col. 10, lines 41-42, and 46-47). Also, the microcapsules of Siebert are coated for extended release. (Siebert, col. 35). Thus, one of skill would expect that uncoated microcapsules with a medicament having an unpleasant taste would not taste good.

Furthermore, Siebert discloses and employs sweeteners and flavoring agents. (See col. 10, lines 19-20). In Example 1 of Siebert, not only is the active ingredient coated, the tablet is prepared from a blend which includes aspartame. (col. 11, lines 15 and 37).

Accordingly, since Siebert provides no reason to exclude the taste masking components, and every reason why they would be needed so as to materially affect the taste of an unpleasant medicament, Applicants submit that Siebert does not render the presently claimed invention obvious.

iii. The Shimono Declaration has been improperly dismissed.

The Examiner dismisses the Shimono Declaration as not being "commensurate in scope with the claims". (Office Action, page 9). The Examiner indicates that the Declaration is not persuasive because both formulations showed taste masking and that the taste masking properties are suggested in Siebert.

Applicants remind the Examiner that it is legal error to decline to give Declaration evidence, or other evidence of unobviousness, meaningful consideration. *In re Sullivan,* 498 F3d 1345, 84

USPQ2d 1034 (Fed. Cir. 2007). Applicants submit that the Examiner has improperly interpreted the results shown in the Declaration, and improperly characterized the teachings of Siebert.

First, the Examiner has improperly interpreted the results of the Declaration. The Examiner says that both formulations show taste masking. However, granules of the claimed invention using methylcellulose and mannitol **completely** and clearly masked the taste of the medicament and the unpleasant taste was not felt. In contrast, for granules using the combination of microcrystalline cellulose and mannitol of the prior art the "masking effect was exhibited" but the unpleasant taste was felt. (Shimono Declaration, page 4). That is, microcrystalline cellulose was not as effective as methylcellulose in masking unpleasant taste.

Moreover, Applicants submit that the Declaration is commensurate in scope with the claims because it presents evidence of the taste-alleviating properties in eight different unpleasant tasting medicaments when used in the inventive formulation. Thus, Applicants submit that the evidence supports the scope of the claims.

Thus, Applicants submit that the Examiner has improperly interpreted the data presented in the Shimono Declaration. Applicants request that this evidence be properly considered and submit that it overcomes any showing of prima facie obviousness which may have been established. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

Applicants also point out that, as discussed above, the taste-masking effect of the combination of methylcellulose and mannitol is NOT addressed in Siebert, and Siebert provides every indication that a flavoring agent or sweetener would be required if coating was not performed. Thus, Applicants submit that Siebert does not provide any reasonable expectation that the combination of methylcellulose and mannitol, in the absence of a flavoring agent, sweetener or coating, would mask the unpleasant taste of the medicament. Accordingly, Applicants submit that the Examiner has improperly characterized the teachings of Siebert, and used this interpretation to dismiss the Shimono Declaration. For this additional reason, Applicants request reconsideration and withdrawal of the rejection.

***Siebert, Depui, and Yoshinari* (and *Shirai*)**

The Examiner rejects claims 8-10, 18, and 21 as unpatentable over Siebert et al. in view of Depui et al., (U.S. Pat. No. 6368625) and Yoshinari et al. (US. Pat. No. 6235947). Applicants respectfully traverse.

As discussed in the past responses neither Depui or Yoshinari remedies the deficiencies of Siebert. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Applicants submit that the present application claims subject matter free of the prior art. The favorable actions of withdrawal of the standing rejections and allowance of the pending claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 

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